DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 21, 2014

Stryker Spine
Garry T. Hayeck, Ph.D.
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K142381
Trade/Device Name: Xia® 3 and Xia® 4.5 Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ
Dated: August 25, 2014
Received: August 28, 2014

Dear Dr. Hayeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142381

Device Name
Xia® 3 Spinal System

Indications for Use *(Describe)*
The Xia® 3 Spinal System is intended for use in the non-cervical spine. When used as an anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the Xia® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative Disc Disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fracture of dislocation)
- Spinal stenosis
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

The 5.5 mm rods from the Stryker Spine Radius™ Spinal System and 6.0 mm Vitallium rods from the Xia® Spinal System are intended to be used with the other components of the Xia® 3 Spinal System.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Xia® 3 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 3 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142381

Device Name
Xia® 4.5 Spinal System

Indications for Use *(Describe)*
The Xia® 4.5 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation for the following indications:

• Degenerative Disc Disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
• Spondylolisthesis
• Trauma (i.e. fracture of dislocation)
• Spinal stenosis
• Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Tumor
• Pseudarthrosis
• Failed previous fusion

The Stryker Spine DIAPASON™ Spinal System, Opus™ Spinal System, and Xia® 4.5 Spinal System can be linked to the Xia® 4.5 Spinal System via the rod-to-rod connector when used for the aforementioned indications in skeletally mature patients as an adjunct to fusion.

Except for the staples, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the Xia® 4.5 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 4.5 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary: Xia® 3 and Xia® 4.5 Spinal Systems	
Submitter	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person	Garry T. Hayeck, Ph.D. Senior Regulatory Affairs Specialist Phone: 201-760-8043 Fax: 201-760-8406 E-mail: garry.hayeck@stryker.com
Date Prepared	October 2, 2014
Trade Names	**1. Xia® 3 Spinal System** **2. Xia® 4.5 Spinal System**
Common Name	**1. Xia® 3 Spinal System** Spinal Fixation Appliances **2. Xia® 4.5 Spinal System** Spinal Fixation Appliances
Proposed Class	**1. Xia® 3 Spinal System** Class III **2. Xia® 4.5 Spinal System** Class III
Classification Name, Codification	**1. Xia® 3 Spinal System** • Spinal Interlaminal Fixation Orthosis, 21 CFR § 888.3050 • Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060 • Pedicle Screw Spinal System, 21 CFR § 888.3070 (b) (1) & (b) (2) **2. Xia® 4.5 Spinal System** • Spinal Interlaminal Fixation Orthosis, 21 CFR § 888.3050 • Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060 • Pedicle Screw Spinal System, 21 CFR § 888.3070 (b) (1) & (b) (2)
Product Codes	**1. Xia® 3 Spinal System** OSH, NKB, KWP, KWQ, MNH, MNI **2. Xia® 4.5 Spinal System** OSH, NKB, KWP, KWQ, MNH, MNI
Predicate Devices	**1. Xia® 3 Spinal System** • Primary Predicate: Medtronic Sofamor Danek, CD HORIZON® Spinal System: K140276 • Additional Predicate: Stryker Spine Xia® 3 Spinal System: K113666, 133188 **2. Xia® 4.5 Spinal System** • Primary Predicate: Medtronic Sofamor Danek, CD HORIZON® Spinal System: K140276 • Additional Predicate: Stryker Spine Xia® 4.5 Spinal System: K121342, 133188
Device Description	**1. Xia® 3 Spinal System** The Xia® 3 Spinal System is comprised of screws, blockers, and

	hooks that affix rods and connectors to vertebrae of the spinal column for purposes of stabilization, or corrective action through the application of force. **2. Xia® 4.5 Spinal System** The Xia® 4.5 Spinal System is comprised of monoaxial and polyaxial bone and reduction screws, hooks, dual staples, and blockers that affix rods, rod-to-rod connectors, and cross connectors to vertebrae of the spinal column.
Indications for Use	**1. Xia® 3 Spinal System** The Xia® 3 Spinal System is intended for use in the non-cervical spine. When used as an anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the Xia® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative Disc Disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) • Spondylolisthesis • Trauma (i.e. fracture of dislocation) • Spinal stenosis • Curvatures (i.e., scoliosis, kyphosis, and/or lordosis) • Tumor • Pseudarthrosis • Failed previous fusion The 5.5 mm rods from the Stryker Spine Radius™ Spinal System and 6.0 mm Vitallium rods from the Xia® Spinal System are intended to be used with the other components of the Xia® 3 Spinal System. When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Xia® 3 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 3 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. **2. Xia® 4.5 Spinal System** The Xia® 4.5 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation for the following indications: • Degenerative Disc Disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)

	• Spondylolisthesis • Trauma (i.e. fracture of dislocation) • Spinal stenosis • Curvatures (i.e., scoliosis, kyphosis, and/or lordosis) • Tumor • Pseudarthrosis • Failed previous fusion The Stryker Spine DIAPASON™ Spinal System, Opus™ Spinal System, and Xia® 4.5 Spinal System can be linked to the Xia® 4.5 Spinal System via the rod-to-rod connector when used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. Except for the staples, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the Xia® 4.5 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia® 4.5 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
Summary of Technological Characteristics	**1. Xia® 3 Spinal System** The subject Xia® 3 Spinal System shares the same materials, geometries, and fundamental scientific technologies as the predicate Xia® 3 Spinal System. None of the aforementioned characteristics have been altered, augmented, or otherwise changed. **2. Xia® 4.5 Spinal System** The subject Xia® 4.5 Spinal System shares the same materials, geometries, and fundamental scientific technologies as the predicate Xia® 4.5 Spinal System. None of the aforementioned characteristics have been altered, augmented, or otherwise changed.
Summary of Performance Data	This submission seeks to build upon predicate Xia® 3 and Xia® 4.5 Spinal Systems through expansion of indications only. Therefore, no additional performance data is necessary.
Conclusion	**1. Xia® 3 Spinal System** The devices of the subject Xia® 3 Spinal System are equivalent in materials, geometries, and intended use to the previously cleared Xia® 3 Spinal System and CD Horizon System. The expanded indications of the Xia® 3 Spinal System are identical to the indications of the predicate CD Horizon System. We therefore conclude that the subject Xia® 3 Spinal System is substantially equivalent to the identified predicate systems. **2. Xia® 4.5 Spinal System**

	The devices of the subject Xia® 4.5 Spinal System are equivalent in materials, geometries, and intended use to the previously cleared Xia® 4.5 Spinal System and CD Horizon System. The expanded indications of the Xia® 4.5 Spinal System are identical to the indications of the predicate CD Horizon System. We therefore conclude that the subject Xia® 4.5 Spinal System is substantially equivalent to the identified predicate systems.